K092313

5. 510(k) Summary - Revision

NOV - 4 2009

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
FDA Establishment Registration #: 2523676

Contact: Susan Olinger, J.D.
Corporate Vice President, Regulatory Affairs
Phone: 610.596.2517

DEVICE MANUFACTURER:

B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen GERMANY
FDA Establishment Registration #: 9610825

DEVICE NAME: The Perfusor® Space Infusion Syringe Pump System

COMMON OR USUAL NAME: Infusion Pump

DEVICE CLASSIFICATION: Class II per Code of Federal Regulation Title 21 §880.5725: Infusion Pump, product code FRN and PCA Infusion Pump, product code MEA

CLASSIFICATION PANEL: General Hospital

PREDICATE DEVICE: The Perfusor® Space Infusion Syringe Pump System is of comparable type and is substantially equivalent to the original submission of the The Perfusor® Space Infusion Syringe Pump System marketed under cleared 510(k) K062699. The predicate device for barcode and out-bound wireless data transmission functionalities is B. Braun Medical Inc. Outlook® Safety Infusion System, marketed under cleared 510(k) K011975. The predicate device for PCA functionality is the MEDLEY™ PCA Module marketed by ALARIS Medical Systems Inc. under cleared 510(k) K032233.

DEVICE DESCRIPTION: The Perfusor® Space Infusion Syringe Pump System includes an external transportable electronic syringe infusion pump and pump accessories. B. Braun Medical Inc. has taken great efforts in consulting with groups of actual users of infusion systems as well as hospital administrations from pharmacists to information technology professionals to develop barcode, out-bound wireless data transmission and PCA features that not only enhance the administration of infusions but are also tools in the development of medication error reduction programs while ensuring the validity of transferred data. The Perfusor® Space Infusion Syringe Pump System can be customized to meet the needs of a particular institution by allowing facilities to enable or disable particular aspects of the bar coding and wireless features, such as nurse ID matching, or by assigning dose or rate limits to particular medications.

Although the only additions to the The Perfusor® Space Infusion Syringe Pump System are barcode, out-bound wireless data transmission and PCA functionality, for convenience of review, the device description may include previously cleared features*

The mechanics of the The Perfusor® Space Infusion Syringe Pump System have not changed since the original submission.

The Perfusor® Space Infusion Syringe Pump System utilizes a swivel-drive pumping mechanism and is intended to provide infusions of parenteral fluids. The Perfusor® Space Infusion Syringe Pump System is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments. A trained Biomedical Technician must perform a complete set-up of the pump prior to use in a clinical setting.

The system is intended to provide intermittent or continuous flow of parenteral fluids to the patient. Parenteral fluids may include standard fluids and/or medications indicated for infusion as well as blood and blood products.

SpaceStation with SpaceCom

The B. Braun Space Station is a 12V DC or battery powered flexible docking and communication system for the medical workplace, in particular the intensive medical care. It serves the perspicuous accommodation of the infusion and infusion-syringe pumps Infusomat® Space and Perfusor® Space.

SpaceCom is a communication software that has been integrated into the SpaceStation. SpaceCom supports different interfaces like Ethernet, PS2-Keyboard, Serial, USB ports and PCMCIA network card. For bar-coding, a barcode image reader can be connected to the PS2-Keyboard or USB interface. The pumps are connected with connectors on the inner backside to the SpaceStation. These connectors provide the voltage supply, distribute the addresses in the Space system via a serial interface, transfer data via a bus system (CAN bus) and transmit a staff call, which may be pending.

The Perfusor® Space Infusion Syringe Pump System must be housed in a SpaceStation that has SpaceCom software installed in order to accomplish the advanced features of bar coding and out-bound wireless data transmission. (SpaceStations are available with or without SpaceCom).

The software communication (CAN bus) allows out-bound flow of information from the infusion pump to an existing hospital information management system. The PCMCIA network card resides in the SpaceStation with SpaceCom. All data transmitted must use the B. Braun information protocol for proprietary data exchange.

The implementation of the PCA feature furthers B. Braun's vision that one pump system can be used throughout an entire facility. The intent of B. Braun is pain therapy management, not only to add a new "pain pump" feature to the existing platform, but to facilitate the hospital-wide management of post-operative pain treatment. Having one system that may be used to administer a wide variety of infusion therapies allow healthcare professionals the benefit of only having to learn one device hospital-wide. The use of one device house-wide helps to ensure consistency in infusion protocols. Medication delivery will be enhanced by understanding and using the advanced features of the

Perfusor® Space and will optimize asset utilization within a healthcare institution. Increased functionality and data acquisition of the Perfusor® Space Infusion Syringe Pump System support medication error reducing programs and can be used to audit the effectiveness of those programs.

Like the predicate device, the Space Cover/Comfort is a feature of the Perfusor Space Syringe Pump System. The Space Cover/Comfort provides a "top" for the Space Station with a battery indicator and audible/visual alarm that functions as a back up to the pump.

INDICATIONS FOR USE: The Perfusor® Space Infusion Syringe Pump System is an electrical, external, syringe infusion pump system indicated for use with adults, pediatrics and neonates and is intended to provide infusions of parenteral fluids/medications, blood and blood products indicated for infusion through FDA approved routes of administration.

SUBSTANTIAL EQUIVALENCE:

The Perfusor® Space Infusion Syringe Pump System is of comparable type and is substantially equivalent to the original submission of the Perfusor® Space Infusion Syringe Pump System marketed under cleared 510(k) K062699. The predicate device for barcode and out-bound wireless data transmission functionalities is B. Braun Medical Inc. Outlook Safety Infusion System, marketed under cleared 510(k) K011975. The predicate device for PCA functionality is the MEDLEY™ PCA Module marketed by ALARIS Medical Systems Inc. under cleared 510(k) K032233.

The subject device is a computer- controlled electrical, external, syringe infusion pump composed of injection molded thermoplastic components. The components of the subject and all non-solution contact parts. The subject and predicates have implemented the advanced features of infusion therapies in a similar manner by developing communication protocols that send and receive infusion data in a barcode or wireless (out-bound) format. The software communication (CAN bus) allows flow of information from the infusion pump to an existing hospital information management system. The PCMCIA network card resides in the SpaceStation with SpaceCom. All data

transmitted must be use the B. Braun proprietary information protocol, ensuring the integrity of data received or sent.

The included accessories of the Perfusor® Space Infusion Syringe Pump System are similar to the predicate devices in that they all offer the clinician maximum flexibility in providing infusion therapy. The subject and predicate systems provide possibilities to clean up and organize the patient bedside by storage of pumps in a filing and communication system. This filing and communication system provides central power supply to the single pumps and tubing retainers to prevent IV line confusion. Also the subject and the predicate provide a means for easy transportation of the modules as well as of the system. Additionally the subject and predicate devices are used to customize the menu items and drug library parameters for each facility. The barcode readers and PCA button accessories are similar in that they both allow for ease of patient use and safeguard the controlled medications being administered.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV - 4 2009

Susan Olinger, J.D.
Corporate Vice President, Regulatory Affairs
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, Pennsylvania 18109-9341

Re: K092313
Trade/Device Name: The Perfusor® Space Infusion Syringe Pump System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, MEA
Dated: July 27, 2009
Received: August 25, 2009

Dear Dr. Olinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K092313

Device Name: The Perfusor® Space Infusion Syringe Pump System

Indications For Use:

The Perfusor® Space Infusion Syringe Pump System is an electrical, external, syringe infusion pump system indicated for use with adults, pediatrics and neonates and is intended to provide infusions of parenteral fluids/medications, blood and blood products indicated for infusion through FDA approved routes of administration.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for AC Anthony Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092313